

## **REMARKS**

Claims 1-8, 10-12, 15-18, and 26-94 were previously pending in this application. By this response, Applicant amends claims 1, 7, 8, 10, 12, 32, 33, 34, 38, 49, 52, 53, 55, 69, 74, 75, 78, 79, 81, and 92 and cancels claims 3, 4, 5, 43, 54, 58, 59, 80 and 85. As a result, claims 1-2, 6-8, 10-12, 15-18, 26-42, 44-53, 55-57, 60-79, 81-84, and 86-94 are pending for examination with claims 1, 38, 53, and 79 as being independent claims. No new matter is added.

### ***Interview***

Initially, Applicant's representatives Walt Norfleet and Jason Honeyman thank the Examiner for the courtesies extended during a teleconference on May 28, 2008. During the interview, amendments to each of claims 1, 38, 53, and 79, previously faxed to the Examiner in a draft response, were discussed in view of U.S. 4,569,647 (McCormick), U.S. 5,817,032 (Williamson), and/or U.S. 41,413,12 (Louder). It was agreed that the proposed amendments distinguish each of McCormick, Williamson, and Louder, as applied in the Office Action mailed on February 22, 2008.

Support for the term "pipette", as used in an automated system, was also discussed. Applicant pointed out that the use of a pipette is described in paragraph 0036 of the present application (column 9, lines 10-14 of the parent patent U.S. 6,913,921 – hereinafter "the '921 patent"). Specifically, the present application describes that cell sample and reagents may be delivered by pipetting. Additionally, paragraph 0038 of the present application (which is actually the very next paragraph in the '921 patent) teaches that the apparatus of the present invention can be configured for automation such that a person of ordinary skill in the art would appreciate that aspects of the invention include automated delivery with a pipette or pipette tip, as is recited in various claims.

### ***Priority and Objections to the Specification***

Claims 4 and 5 were objected to for not being supported by the written description of the '921 patent, to which the present application claims priority. The specification was also objected to for failing to provide antecedent basis for the claims 4 and 5. Claims 4 and 5 are hereby cancelled without prejudice in order to expedite allowance of this case, such that these objections are moot. Claims 3, 43, 54, 58, 59, 80 and 85 are additionally cancelled without prejudice. Each

of the claims as pending are believed to be fully supported under 35 USC §112 by the specification of the present application and the ‘921 patent, as discussed below.

### ***Rejections Under 35 USC §112***

Claims 16, 17, 26-42, 44-53, 55-57, 60-79, 81-84, and 86-94 stand rejected under 35 USC §112, 1<sup>st</sup> paragraph as failing to comply with the written description requirement. In particular, it is mentioned in the Office Action that the Applicant did not previously point out where claims 16, 17, 26-42, 44-53, 55-57, 60-79, 81-84, and 86-94 find support, such that the claim amendments and new claims are presumed to be new matter (see MPEP 2163.04 (I)(B)).

Applicant details below where various features of each of the pending claims finds support within the present application and the ‘921 patent. This is believed to satisfy the requirement set forth at MPEP 2163.04 (I)(B). Accordingly, withdrawal of these rejections is respectfully requested.

Each of claims 1, 38, 93, and 94 relate, at least in part, to automatic delivery of a cell sample to a filter. Some examples of how this may be accomplished are discussed in paragraphs 0038 and 0040 of the present application (similarly, the paragraphs that begin at column 9, line 30 and column 10, line 10 of the ‘921 patent).

Claims 2 and 57 specify that the first reagent is alcohol. This is described at least in the paragraph 0039 of the present application (similarly, the paragraph that begins at column 9, line 58 of the ‘921 patent).

Claims 6 and 60 describe that the embedding solution is liquefied paraffin. These claims find support at least in paragraph 0039 of the present application (similarly, the paragraph beginning at column 9, line 58 of the ‘921 patent), which describes that melted paraffin is pulled through a filter.

Claims 7, 8, 61, and 62 relate to staining a captured portion of a cell sample, which is described in paragraph 0051 of the present application (similarly, the paragraph that begins at column 11, line 47 of the ‘921 patent).

Claims 10 and 63 relate to the use of a preservative, and claims 11 and 64 specify that the preservative is formalin. Support for these claims may be found at least in paragraph 0028 of the present application (similarly, the paragraph beginning at column 6, line 38 of the ‘921 patent).

Claims 12 and 65 relate to flowing a decalcifying solution and find support at least in paragraph 0028 of the present application (similarly, the paragraph beginning at column 6, line 38 of the ‘921 patent).

Claims 15 and 66 relate, at least in part, to the use of a negative pressure. Some examples that utilize negative pressure are described in paragraphs 0036, 0038, and 0040 of the present application (similarly, the paragraphs beginning at column 8, line 61; column 9, line 30; and/or column 10, line 10 of the ‘921 patent).

Each of claims 16, 17, 39, 40, 41, 42, 67, 82, 83, and 84 relate, at least in part, to the use of a pipette or a pipette tip. One example of how a pipette may be used is described in paragraph 0036 of the present application (similarly, the paragraph that begins at column 8, line 61 of the ‘921 patent). Also, as discussed above, paragraph 0038 of the present application teaches that the apparatus of the present invention can be configured for automation (similarly, see col. 9, lines 30-31 of the ‘921 patent) such that a person of ordinary skill in the art would appreciate that aspects of the invention include automated delivery with a pipette or pipette tip.

Claims 18 and 68 relate, at least in part, to the use of a positive pressure. Some examples that utilize positive pressure are described in paragraphs 0040, 0041, and 0048 of the present application (similarly, see the paragraphs beginning at column 10, lines 10 and 27; and at column 11, line 28 of the ‘921 patent).

Claims 26, 31, 47, 55, 56, 71, and 81 relate, at least in part, to solidifying an embedding solution, cooling a filter, or cooling embedding solution. Some examples of these features are mentioned in paragraphs 0034 and 0039 of the present application (similarly, the paragraphs that begin at column 8, line 31 and column 9, line 58 of the ‘921 patent).

Claims 26, 44, 69, and 86 describe either separating a filter from an embedded cell block or removing a filter from a cassette to expose a surface of an embedded cell block. One example of a filter that is peeled away from an embedded cells is described at paragraph 0039 of the present application (similarly, the paragraph beginning at column 9, line 58 of the ‘921 patent).

Claims 27, 45, 70, and 87 relate to re-melting at least a portion of a surface of an embedded cell block. Paragraph 0052 of the present application (similarly, the paragraph beginning at column 11, line 66 of the ‘921 patent) describes one example of how this may be accomplished.

Each of claims 28 and 71 describe cooling a surface of an embedded cell block.

Paragraph 0052 of the present application (similarly, the paragraph beginning at column 11, line 66 of the ‘921 patent) describes one example of how this may be accomplished.

Claims 29 and 72 describe a spacer that is separated from an embedded cell block. In paragraph 0039 of the present application (the paragraph beginning at column 9, line 58 of the ‘921 patent), one example of a spacer (a gasket) is described.

Each of claims 30, 46, 53, and 79 relate, at least in part, to heating a filter, heating a thermally conductive filter support, and/or heating embedding solution. Paragraph 0034 of the present application (the paragraph beginning at column 8, line 31 of the ‘921 patent) provides support for at least one example of how this may be accomplished.

Claims 31, 47, 55, 56, and 81 mention cooling the filter or cooling embedding solution, which is described in paragraph 0034 of the present application (similarly, the paragraph beginning at column 8, line 31 of the ‘921 patent).

Claims 32, 48, and 73 describe monitoring a level of at least one of a first reagent, a second reagent, or an embedding solution. Various ways to accomplish this are described in paragraphs 0042, 0043, 0044, 0045, and 0046 of the present application (similarly, the paragraphs beginning at column 10, lines 39, 53, and 62 and at column 11, lines 1 and 8 of the ‘921 patent).

Claims 33, 49, 74, and 88 relate to keeping a portion of a cell sample immersed in at least one of first and second reagents or delivering reagent such that a portion of a cell sample remains immersed. These claims find support at least in paragraph 0036 of the present application (similarly, the paragraph beginning at column 8, line 62 of the ‘921 patent), which describes that the meniscus should not pass through the filter. Additionally, paragraph 0042 of the present application (similarly, the paragraph beginning at column 10, line 39 of the ‘921 patent) describes that the meniscus of the fluid level may be monitored.

Claims 34, 50, 75, and 89 relate to a waste container and comparing a weight of a reagent. Waste containers are described, in general, in paragraphs 0038 and 0039 of the present application (similarly, the paragraphs beginning at column 9, lines 30 and 58 of the ‘921 patent). Additionally, paragraph 0040 of the present application (similarly, the paragraph beginning at column 11, line 8 of the ‘921 patent) describes weighing effluent (e.g., reagents) that have passed through a filter.

Claims 35, 51, 76, and 90 relate to using a combination of positive and negative pressures. One possible example of using a combination of positive and negative pressures is described in paragraph 0040 of the present application (similarly, the paragraph beginning at column 10, line 10 of the '921 patent).

Each of claims 36, 77, and 91 relate to monitoring a flow rate of reagent and/or embedding solution. Paragraphs 0046 of the present application (similarly, the paragraph beginning at column 11, line 8 of the '921 patent) describes one example of flow rate monitoring.

Claims 37, 52, and 92 relate to monitoring a refractive index of reagent and/or embedding solution. One example of monitoring a refractive index is described in paragraph 0048 of the present application (similarly, the paragraph that begins at column 11, line 25 of the '921 patent).

### ***Rejections under 35 USC §103***

Claims 1-2, 6-8, 10-12, 15-18, 26-42, and 44-52 stand rejected under 35 USC §103(a) as being unpatentable over McCormick in view of Williamson. Claims 53, 55-57, 60-79, 81-84, and 86-94 stand rejected under 35 USC §103(a) as being unpatentable over McCormick in view of Williamson in further view of Louder.

### **Independent claim 1**

As amended, independent claim 1 recites, among other aspects, automatically delivering a cell sample to a filter, at least a portion of the cell sample, that is otherwise physically unrestrained, being captured by the filter. Claims 1, 7, 8, 10, 12, 32, and 33 are amended to be consistent with the language of claim 1, and/or to address informalities. Support for these amendments may be gleaned at least from paragraph 0032 of the present application (similarly, the paragraph that begins at column 7, line 59 of the '921 patent), which describes that cells may be automatically positioned at approximately the plane at which a microtome blade will cut a cell block.

Neither McCormick nor Williamson, alone or in combination, teach or suggest at least a portion of a cell sample, that is otherwise physically unrestrained, being captured by a filter, as agreed during the interview and as recited by claim 1.

McCormick discloses tissue samples 26 that are immobilized against a porous material 20 in the molds 16, either with an insert 86 of spongy material (see generally col. 4, line 58-60 and Fig. 3) or by soaking the tissue sample in gelatin that adheres the sample to the porous material

(see generally col. 5, lines 4-7). The use of an immobilizer may be particularly important for McCormick, which seeks to position the tissue samples in an orientation most appropriate for microtome slicing (see generally col. 4, lines 55-58), hence the provision of an immobilizer. The disclosed preferred flow path of McCormick is upwardly through the molds 26 in a manner that would urge any otherwise physically unrestrained samples away from the porous material (i.e., filter) and out of position for microtome slicing.

Williamson also describes immobilizing a sample on a filter and processing the sample in an automated process (see generally, the abstract). As shown and discussed with reference to step 5 of FIG. 8 in Williamson, a sample may be immobilized on a filter, like that of FIG. 1, with cyanoacrylate, ultraviolet curing dry adhesive, coatings with protein affinity, or Dry Net ballistic particle deposition (see col. 16, lines 8-26). In other embodiments, a sample may be immobilized to a cassette with hooks 24, pins, and gripping elements, as shown in FIG. 3 and discussed at col. 4 lines 64-67. Williamson does not teach or suggest processing a sample that is physically unrestrained, as is now claimed. To the contrary, unless immobilized, samples in the system taught by Williamson would move away from the filter when stored in the rack or processed in a tissue processor, as shown in FIG. 11.

A person of ordinary skill in the art would actually be led away from utilizing otherwise physically unrestrained particles, based on the teachings of McCormick or Williamson. For at least the above described reasons, claims 1-2, 6-8, 10-12, 15-18, and 26-37 patentably distinguish over McCormick in view of Williamson. Accordingly, withdrawal of these rejections is respectfully requested.

#### Independent claim 38

As amended, independent claim 38 recites, among other aspects, delivering automatically a cell sample to the filter, at least a portion of the cell sample that is otherwise physically unrestrained being captured by the filter.

As discussed above with respect to claim 1, neither McCormick nor Williamson teach or disclose processing a cell sample that is otherwise physically unrestrained, such that the rejections of claims 38-42 and 44-52 are overcome. Accordingly, withdrawal of these rejections is respectfully requested.

Independent claims 53 and 79

Each of independent claims 53 and 79 are amended to incorporate the subject matter of claims 54 and 80 respectively.

As amended, independent claim 53 recites, among other aspects, flowing an embedding solution through a captured portion of a cell sample, at least a portion of the embedding solution flowing through a filter and a thermally conductive filter support. The method also comprises heating the embedding solution through the thermally conductive filter support to promote the flow of embedding solution through the filter.

Independent claim 79, as amended, recites providing a cassette that includes a filter and a thermally conductive filter support. The method also comprises heating embedding solution through the thermally conductor filter support to promote the flow of embedding solution through the filter.

As discussed during the interview, neither McCormick, Williamson, nor Louder teach or disclose a thermally conductive filter support, much less heating an embedding solution through a thermally conductive filter support to promote the flow of embedding solution through a filter, as now recited by claims 53 and 54. In this respect, the rejections of claims 53, 55-57, 60-79, 81-84, and 86-94 are believed to be overcome. Accordingly, withdrawal of these rejections is respectfully requested.

***Double Patenting***

Claims 1-2, 6-8, 10-12, 15-18, 26-42, 44-53, 55-57, 60-79, 81-84, and 86-94 stand rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1-18 of the '921 patent in view of McCormick and Williamson, either alone or in further view of Louder. Without acceding to propriety of these rejections, Applicant will submit a Terminal Disclaimer, upon an indication of the allowability of the pending claims.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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